

K090014

APR 09 2009

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510(k) Submission Report – Section IV 510(k) Summary
Report SN: A2008-041-064

Caremate

Section IV 510(k) Summary

Caremate Medical Device Co., Ltd
Caremate Sphygmomanometer with Stethoscope
(As Required by CFR 807.92)

Date of Preparation December 29, 2009

510(k) Sponsor Caremate Medical Device Co., Ltd
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Submission Correspondent Ms. Xiaoming Hong / Mr. Li Fu
Shanghai Mid-Link Consulting Co., Ltd
Suite 8D, No.19, Lane 999
Zhongshan No.2 Road(S), Shanghai, 200030, China

Proposed Device Device Trade Name: Caremate Sphygmomanometer with Stethoscope;
Models: CM-BPM and CM-PBPM;

Classification Name: blood pressure cuff;
Product Code of Sphygmomanometer: DXQ;
Regulation Number of Sphygmomanometer: 870.1120;
Device Class of Sphygmomanometer: II (510(k));
Review Panel: Cardiovascular;

Classification Name: stethoscope, manual;
Product Code of Stethoscope: LDE;
Regulation Number of Stethoscope: 870.1875;
Device Class of Stethoscope: I (510(k) Exempt)
Review Panel: Cardiovascular

Caremate

Intended Use	Caremate Sphygmomanometer with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospitals or at home to monitor both systolic and diastolic pressure by detecting Korotkoff sound. This product is only for adult use.
Device Description	<p>The proposed device, Caremate Sphygmomanometer with Stethoscope, is a non-invasive and non automated device intended to measure the blood pressure. It contains of a cuff with inflatable bladder and an aneroid manometer to measure the pressure, as well as a stethoscope for detecting the Korotkoff sound; In addition, an end valve, an air release valve and a bulb are included to complete its function.</p> <p>Caremate Sphygmomanometer with Stethoscope has two models, CM-BPM and CM-PBPM. They are following the same design principle and same components. The only differences are that the bulb and the aneroid manometer are connected together. The operator can held them in one hand. This design feature facilitates the using of this device and will not affect the performance.</p> <p>This product is provided non-sterile and only for adult use.</p>
Non-Clinical Testing Summary	Laboratory testing was conducted to validate and verify that the proposed device, Caremate Sphygmomanometer with Stethoscope, both CM-BPM and CM-PBPM met all design specifications and was substantially equivalent to the predicate device.
Clinical Testing Summary	No Clinical Information is required.
Predicate Identification	<p>K081951 cleared in Aug 15, 2008</p> <p>Aneroid Sphygmomanometer Model KT-A01 with Stethoscope</p> <p>Manufacturer: Wenzhou Kindcare Import & Export Co., Ltd</p>
SE Conclusion	The Caremate Sphygmomanometer with Stethoscope (CM-BPM and CM-PBPM) is claimed to be Substantially Equivalent (SE) to Aneroid Sphygmomanometer Model KT-A01 with Stethoscope (K081951 cleared in Aug 15, 2008).



APR 09 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Caremate Medical Device Co., Ltd.
c/o Ms. Xiaoming (Diana) Hong
Shanghai Midlink Business Consulting Co., Ltd.
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Zhongshan No. 2 Road (S)
Shanghai, China 200030

Re: K090014

Trade/Device Name: Caremate Sphygmomanometer with Stethoscope, Models CM-BPM and CM-PBPM

Regulation Number: 21 CFR 870.1120

Regulation Name: Blood Pressure Cuff

Regulatory Class: Class II (Two)

Product Code: DXQ

Dated: Undated

Received: April 3, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1090014

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510(k) Submission Report – Section III Indication for Use Statement
Report SN: A2008-041-064

Caremate

Section III Indication for Use Statement

510(k) Number:

Device Name: Caremate Sphygmomanometer with Stethoscope

Indications for Use:

Caremate Sphygmomanometer with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospitals or at home to monitor both systolic and diastolic pressure by detecting Korotkoff sound. This product is only for adult use.


Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number 1090014